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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/744,748 | 01/29/2001 | Hisashi Narimatsu | 1241.17 | 4282 |

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| EXAMINER |
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RAO, MANJUNATH N

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| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|---|--|
| Office Action Summary | Application No. 09/744,748 | Applicant(s) NARIMATSU ET AL. | |
| | Examiner Manjunath N. Rao, Ph.D. | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) 19-23,25-50 and 54-75 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 and 51 is/are allowed.
- 6) ☒ Claim(s) 1,3-18,24,52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-75 are currently pending in this application. Claims 1-18, 24, 51-53 are now under consideration. Claims 19-23, 25-50, 54-75 remain withdrawn from consideration as being drawn to non-elected invention.

Applicants' amendments and arguments filed on 4-29-04, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Specifically Examiner has withdrawn the rejections under 35 U.S.C. 112, 2nd paragraph in view of claim amendments. Examiner has also withdrawn the rejection of claims 1, 3-18, 24, 51-53 under 35 U.S.C. 112, 1st paragraph, as non-enabled in view of claim amendments. Rejection of Claims 1-9, 12, 17-18, 24, 51-53 rejected under 35 U.S.C. 102(a) as being anticipated by Kaneko et al. FEBS Letters, Vol. 453, 1999, pages 237-242 (Examiner regrets the inadvertent error in reciting the Kaneko et al. reference as J. Biol. Chem. Vol., 272(34):21357-21363, Aug. 1997, in IDS paper No.6) or Kudo et al. (JBC, Oct 1998, Vol. 273:26729-38 in IDS paper No.6) or Ge et al. (J. Biol. Chem. Vol., 272(34):21357-21363, Aug. 1997) is also withdrawn in view claim amendments and perfecting the foreign priority by submission of English language translations.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 3, 4(a)-18, 24, 52-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3, 4(a)-18, 24, 52-53 are directed to polypeptides having the activity of transferring fucose to an N-acetylglucosamine structure in an N-acetyllactosamine structure existing in a non-reducing terminus of a sugar chain via an alpha 1,3-linkage, but not having a similar activity to transfer fucose to N-acetylglucosamine residue in an alpha 2,3-sialyl N-acetyllactosamine structure. Claims 1, 3-18, 24, 52-53 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides derived from SEQ ID NO:1 or 2 including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid and fragments that have not been disclosed in the specification. No description has been provided of all the polypeptide sequences encompassed by the claims. No information, beyond the characterization of SEQ ID NO:1 and 2 has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The specification does not contain any disclosure of the structure of polypeptide sequences derived from SEQ ID NO:1 or 2, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of structures. Therefore many structurally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus.

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Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Applicants have not specifically addressed the above rejection. It appears that they have concluded that limiting the claims to either mouse or human overcomes the written description rejection as well. However, in view of the claim amendments, Examiner has only withdrawn the non-enablement rejection but continues to maintain the above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 7-8, 10 12-18, 24, 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowe et al. (J. Biol. Chem. Vol., 266(26):17467-17477, Sep. 1991). This rejection is based upon the public availability of a printed publication. Claims 1, 3-5, 7-8, 10 12-18, 24, 52-53 of the instant application is drawn to an enzyme having the activity of transferring fucose to an N-acetylglucosamine structure in an N-acetylactosamine structure existing in a non reducing terminus of a sugar chain via an alpha 1,3-linkage, but not having a similar activity to transfer fucose to N-acetylglucosamine residue in an alpha 2,3-sialyl N-acetylactosamine

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structure isolated from humans or mouse, polynucleotide and vectors encoding said enzyme, host cell comprising said polynucleotides methods of making such polypeptide by culturing said host cells and method of making fucosylated products using said enzyme. Lowe et al. disclose an enzyme with identical properties i.e., having the activity of transferring fucose to an N-acetylglucosamine structure in an N-acetyllactosamine structure existing in a non reducing terminus of a sugar chain via an alpha 1,3-linkage, but not having a similar activity to transfer fucose to N-acetylglucosamine residue in an alpha 2,3-sialyl N-acetyllactosamine structure (see abstract and the entire publication), method of making such polypeptides and use said polypeptide in a reaction to make reaction products. Since applicants have not limited the polypeptide and the polynucleotide encoding the same to any structure, the enzyme claimed and the polynucleotide encoding the same can have any structure and therefore reads on the enzyme disclosed by Lowe et al. Thus Lowe et al. anticipate claims 1, 3-5, 7-8, 10 12-18, 24, 52-53 of this application as written.

In response to the above rejection applicants argue that the enzyme of the application can synthesize the sugar chain having β 1-4GlcNAc(Fuc α 1-3) structure existing in a nonreducing terminus using a sugar chain having Gal β 1-4GlcNAc structure as a substrate and at the same time it cannot synthesize the sugar chain having NeuAC α 2-3Gal β 1-4GlcNAc (Fuc α 1-3) structure using a sugar chain having α 2-3Gal β 1-4GlcNAc structure. In contrast to the above applicants argue that the enzyme described by Lowe's is a counter part of mouse Fuc-TIV which is unable to synthesize the oligosaccharide as above. However, Lowe et al. clearly state

“By contrast, biochemical and flow cytometry analyses suggest that the enzyme cannot efficiently utilize type II acceptor NeuNAc α 2,2Gal β ...to form sialyl Lewis x determinant” (see abstract)

Therefore, irrespective of the applicant's argument, Lowe et al. clearly disclose an enzyme capable of synthesizing Lewis x determinant but not sialyl Lewis x determinant as claimed in claim 1. In support of their argument applicants direct the Examiner's attention to the abstract of Lowe's reference and page 25048, left column lines 7-10. However, it appears that applicants are not referring to Examiner's reference but to some other reference of Lowe's et al. This is because the reference cited by the Examiner (J. Biol. Chem. Vol., 266(26):17467-17477, Sep. 1991) does not have page 25048 and nowhere in the reference said enzyme is referred to as Fuc-IV. On the contrary, the reference of Lowe which applicant refers to is drawn to a novel human fucosyltransferase which capable of efficiently utilizing N-acetyllactosamine to form Gal β 1-4GlcNAc(Fuc α 1 \rightarrow 3) structure and is not the same as that fo the Examiner's reference. Therefore, the above rejection is maintained.

Conclusion

Claims 2 and 51 are allowable.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306/9307 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.


Manjunath N. Rao, Ph.D.
Primary Examiner
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September 24, 2004